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Joanne M. Giesser
MERCK & CO., INC.
P.O. Box 2000
Rahway, NJ 07065-0907

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,820,870

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,820,870, which claims the human biological product Gardasil® (Quadrivalent Human Papillomavirus Recombinant Vaccine), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,199 days (3.3 years).

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,199 days (3.3 years).

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 23, 2007 (72 Fed. Reg. 28979). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2031 - 0) + 184 \\ &= 1,199 \text{ days (3.3 years)}\end{aligned}$$

Since the regulatory review period began May 17, 2000, after the patent issued (October 13, 1998), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,820,870

Granted: October 13, 1998

Original Expiration Date¹: October 13, 2015
Applicant: Joseph G. Joyce, *et al.*
Owner of Record: Merck & Co., Inc.
Title: Recombinant Human Papillomavirus Type 18 Vaccine
Product Trade Name: Gardasil® (Quadrivalent Human Papillomavirus Recombinant Vaccine)
Term Extended: 1,199 days
Expiration Date of Extension: January 24, 2019

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7728
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Raul Tamayo at (571) 272-7728.



Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy RE: Gardasil® (Quadrivalent Human
Food and Drug Administration Papillomavirus Recombinant Vaccine)
10903 New Hampshire Ave., Bldg. 51, Rm. 6222 FDA Docket No.: 2006E-0501
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

¹Subject to the provisions of 35 U.S.C. § 41(b).